CR 25.0

User manual

Point of > Knowledge

AGFA

- *The device must only be operated according to its specifications and its intended use. Any operation not corresponding to the specifications or intended use may result in hazards, which in turn may lead to serious injuries or fatal accidents (for example electric shocks). AGFA positively will not assume any liability in these cases.*
- *The device must only be installed and put into operation under the specified conditions.*

For more information on Agfa products and Agfa HealthCare products, please visit www.agfa.com, your Point of Knowledge.

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Chapter 1

Introducing the CR 25.0

This chapter draws attention to important safety precautions and introduces the CR 25.0.

- ❑ CR 25.0 intended use
- ❑ CR 25.0 features
- ❑ Safety precautions
- ❑ Safety compliance
- ❑ Operating modes
- ❑ Configurations
- ❑ The user interface
- ❑ Switching on the CR 25.0
- ❑ Switching off the CR 25.0

CR 25.0 intended use

This device must only be used to scan exposed X-ray cassettes, containing an erasable image plate (IP). This device is part of a system, consisting of
X-ray cassettes with erasable phosphor image plates, an identification station for the cassettes and a workstation where the resulting digital image information is further processed and routed. This device is intended to be operated in a radiological environment by qualified staff.

CR 25.0 features

The CR 25.0 is a Digitizer for image plates retaining latent X-ray images. It has been developed by Agfa.

- The CR 25.0 accepts one cassette containing one image plate at a time. The CR 25.0:
  - takes the cassette containing the image plate from the cassette slot;
  - removes the image plate from the cassette;
  - scans the image plate;
  - converts the information of the latent image to digital data;
  - transmits the image data to the preview station;
  - erases the image plate and re-inserts it into the cassette;
  - gives the cassette ID data the status ‘erased’;
  - returns the cassette;
  - transmits the digital image data to an image processing station (‘destination’).
- The CR 25.0 allows assigning the status ‘emergency’ to an image.
  The Digitizer gives an image priority to be sent to the image processing station if the “Emergency key” was pressed before inserting an unidentified cassette.
- The CR 25.0 allows re-erasing an image plate before re-using it. In specific cases, this is necessary to prevent ghost images caused by previous exposures or stray radiation from interfering with the image of interest.
- If the CR 25.0 is dedicated to one ID Station, additional features are available:
  - quickly identifying cassettes without the need for an ID Tablet;
  - reading the identification data of a cassette;
  - initializing a cassette, i.e. changing the image plate type.

Safety precautions

General safety instructions

- For software and other technical platforms, and/or if valid in combination with any consumable, which constitute, after installation, a system for the interpretation of medical image data by trained and qualified professionals: it is the user's responsibility to ensure that image quality, display quality, environmental lighting and other possible distractions are consistent with the clinical application.
- Make sure that the CR 25.0 is constantly monitored in order to avoid inappropriate handling, especially by children.
- Only trained service personnel must make repairs. Only authorized service personnel must make changes to the CR 25.0.
- If there is any visible damage to the machine casing, do not start nor use the CR 25.0.
- If you want to connect the CR 25.0 with other devices, components or assemblies and if the technical data do not allow determining whether the combination with these devices, components or assemblies involves hazards, you must consult the respective manufacturers to avoid danger for operating personnel or the environment.
- Do not override or disconnect the integrated safety features.
- As is the case for all technical devices, the CR 25.0 must be operated, cared for and serviced correctly.
- If you don't operate the CR 25.0 correctly or if you don't have it serviced correctly, Agfa-Gevaert is not liable for resulting disturbances, damages or injuries.
- When installing the CR 25.0, care must be taken to ensure that there is either a mains plug or an all-cable disconnecting device in the internal installation fitted near the CR 25.0 and that it is easily accessible.
- If you notice conspicuous noise or smoke, disconnect the CR 25.0 immediately.
- Check that the mains voltage is within the specified range of the self adapting power supply of the machine.

Markings and labels

Always take into account the markings and labels provided on the inside and outside of the machine. A brief overview of these markings and labels and their meaning is given below.

	Safety warning, indicating that the CR 25.0 manuals should be consulted before making any connections to other equipment. The use of accessory equipment not complying with the equivalent safety requirements of this Digitizer may lead to a reduced level of safety of the resulting system. Consideration relating to the choice of accessory equipment shall include: • Use of the accessory equipment in the patient vicinity, • Evidence that the safety certification of the accessory equipment has been performed in accordance with the appropriate IEC 601-1 and IEC 601-1-1 harmonized national standard. In addition all configurations must comply with the medical electrical systems standard IEC 601-1-1. The party that makes the connections acts as system configurator and is responsible for complying with the systems standard. If required contact your local service organization.
	In order to reduce the risk of electric shock, do not remove any covers.
	Caution hot: Keep hands clear from the erasure unit.
	Type B equipment: Indicates that the CR 25.0 complies with the limits for type B equipment.
	Supplementary protective earth connector: Provides a connection between the CR 25.0 and the potential equalization busbar of the electrical system as found in medical environments. This plug should never be unplugged before the power is turned off and the power plug has been removed.
	Intergrounding connector: Provides a connection between the Digitizer and other equipment which might exhibit minor ground potential differences. These differences may degrade the quality of communication between different equipment. Never remove connections to this terminal.
	Protective earth (ground): Provides a connection between the Digitizer and the protective earth of the mains. Do not remove this connection, because this will have a negative influence on the leakage current.

	Power On
	Power Off Note that the power cord has to be disconnected from the wall outlet in order to disconnect the unit entirely from the mains.
	Precautions for use in USA only: Make sure that the circuit is single-phase center-tapped, if the Digitizer is connected to a 240 V/60 Hz source instead of a 120 V/ 60 Hz source.

- You can hurt your fingers if they are caught between the ADC Cassette and the edge of the input slot. Insert the cassette in the input buffer as described in *'Reading an image plate'* on page *29*. At all times, keep your fingers clear of the input slot. As soon as the cassette enters the CR 25.0, release it.

System configuration responsibility

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 601-1-1. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 601-1-1. If in doubt, consult your local service organization.

Safety instructions for laser products

The CR 25.0 is a Class 1 Laser Product. It uses a 2x50 mW laser diode, classification class IIIb.

Under normal operating conditions - when both doors are closed - there can be no laser radiation outside the CR 25.0. It is nonetheless imperative that the local radiation safety regulations regarding the protection of staff against scattered radiation are complied with, if the CR 25.0 is located in the immediate vicinity of an X-ray room.

Open the front left and right door only to solve cassette or image plate jams. When you open either of the doors, the power supply of all critical components is switched off automatically as a precaution.

Observe the Caution instructions on the Optical module label:

CAUTION!
CLASS 3B LASER RADIATION: WHEN OPEN AVOID DIRECT EXPOSURE TO THE BEAM!
CUIDADO!
RAYO LASER CLASE 3B: EVITAR LA EXPOSICIÓN AL HAZ CUANDO LA TAPA ESTÁ ABIERTA.
VORSICHT !
LASERSTRAHLUNG KLASSE 3B: WENN ABDECKUNG GEÖFFNET NICHT DEM STRAHL AUSSETZEN!
ATTENTION!
FAISCEAU LASER CLASSE 3B: QUAND CAPOT OUVERT ÉVITER DE S´EXPOSER AU RAYÓN!

User interventions other than those described in this manual can be hazardous with regard to laser radiation.

Safety compliance

Certificates

The CR 25.0 complies with:

- the general safety regulations:
  EN 60601-1 :1990 / A1:1993, A2:1995, A13:1996,
  EN 60601-1-2 :2001,
  IEC 601-1 :1988/A1 :1991, A2 :1995,
  IEC 601-1-1 / EN 60601-1-1,
  UL 60601-1:2003,
  CAN / CSA C22.2 No.601.1-M90.
- the laser safety regulations:
  EN 60825-1: 1994 / A1:2002, A2:2001,
  DHHS/FDA 21 CFR, Parts 1040.10 and 1040.11,
  ANSI Z 136-1980.
- EN ISO 14971:2000,
  EN 1041:1998,
  EN 980:1996/A1.

❖ *The Digitizer is in compliance with the EG regulation 93/42/EEC Directive (Medical Device).*

Radio Interference Suppression

It is hereby certified that the Digitizer has interference suppression according to the EN 55011 Class B as well as the FCC Rules CR47 Part 15 Class B (North-America).

Short-range devices

EN 300 330-2 V1.1.1
EN 301 489-03 V1.2.1

For USA only:
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. In case the equipment causes harmful interference to other devices, see the User manual for help.

Operating modes

The CR 25.0 can be operated in three modes: operator mode, key-operator mode, and service mode.

Operator mode

The operator mode groups all basic functions which are aimed at radiographers:

- Reading an image plate;
- Reading an emergency image plate;
- Re-erasing an image plate;
- Reading the identification data of a cassette (Dedicated configuration only);
- Changing the image plate type (Dedicated configuration only).

All functions of the operator mode are described in *Chapter 2, 'Basic operation ('Operator mode')'*.

Key-operator mode

The key-operator mode groups advanced functions which are aimed at technicians.

The key-operator mode can be accessed via the Key-operator key on the keypad and is menu-driven. The key-operator functions are described in *Chapter 3, 'Advanced operation ('Key-operator mode')'*.

Service mode

The service mode functions are reserved for trained service personnel. They are password protected.

Configurations

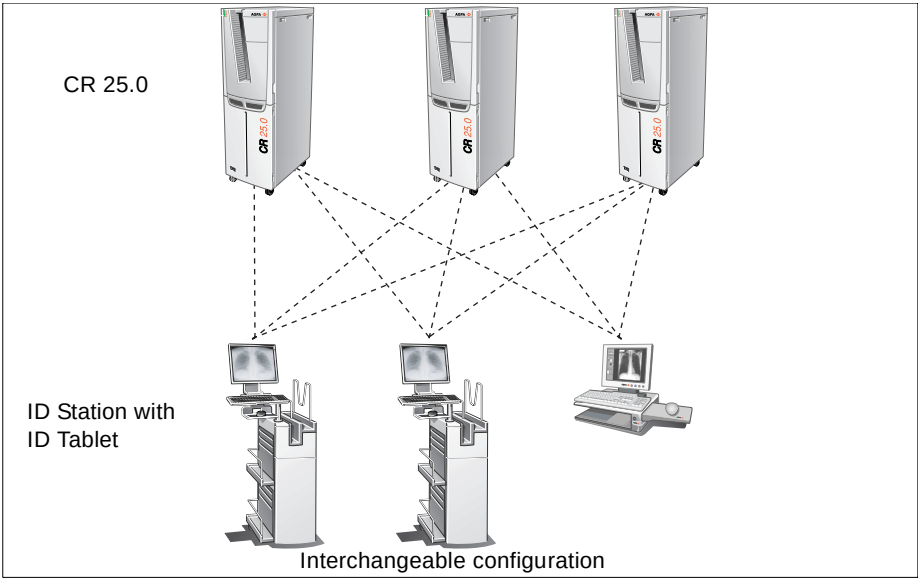
The CR 25.0 can be used in two configurations: either one or more ID Stations serve a range of Digitizers, or one ID Station is dedicated to one Digitizer. For the ID Station a CR User Station with included ID Tablet can be used as well as a stand-alone ID Tablet. The ID Software installed on the PC is slightly different depending on the configuration. For more information, contact your local service organization.

Interchangeable configuration

One or more ID Stations can serve a range of Digitizers, provided that each ID Station has an ID Tablet. There is no physical link required between the ID Station and the Digitizer.

In this configuration, a cassette can be identified via any of the ID Stations and subsequently be scanned using any of the Digitizers. The patient demographic data and examination data are entered via the ID Viewer Software and stored in the memory chip of the ADC cassette via the ID Tablet. As a result the identification data are linked to the cassette and any Digitizer can be used to scan the cassette.

The interchangeable configuration allows the flexible use of several Digitizers and ID Stations depending on the workload.

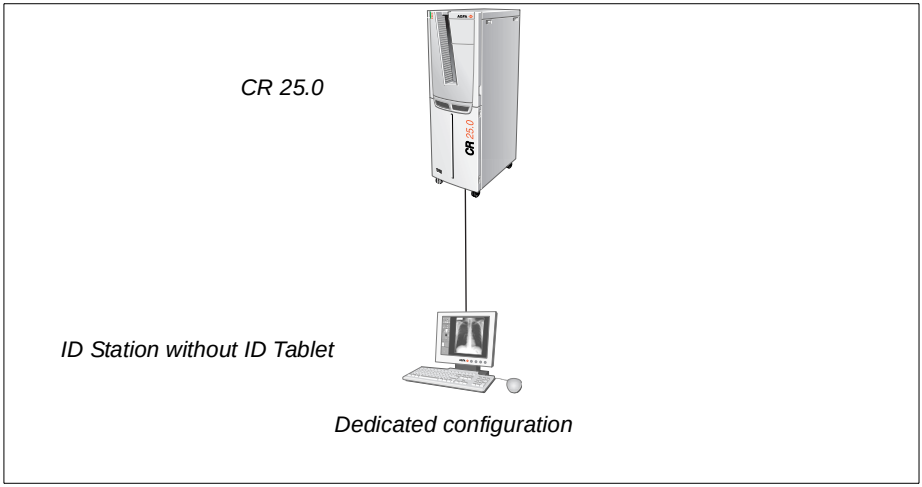


Interchangeable configuration

Dedicated configuration

If one ID Station is dedicated to one Digitizer, cassettes can be identified without using an ID Tablet. The identification data are transmitted from the ID Station to the Digitizer via the network.

The dedicated configuration reduces the time required for identifying and scanning a cassette because both actions can be performed simultaneously.



Dedicated configuration

❖ *In the dedicated configuration, you can still use the CR 25.0 to digitize cassettes which have been identified on an ID Station or a CR User Station.*

The user interface

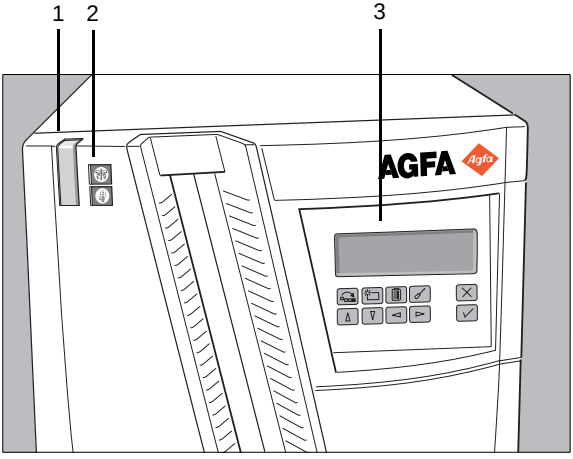
The CR 25.0 has three operation modes:

- the **operator mode** for basic operation;
- the **key-operator mode** for advanced operation;
- the **service mode** reserved for trained service personnel.

The functions of the operator mode are described in *Chapter 2, 'Basic operation ('Operator mode')'*. An overview of the functions of the key-operator mode is given in *'Survey of advanced functions ('Key-operator mode')'* on page *52*. For detailed information on the key-operator mode, refer to the CR 25.0 Reference manual.

The CR 25.0 interfaces with the user via:

- a keypad and a display;
- a status indicator;
- emergency buttons;
- audio signals.



1	Status indicator
2	Emergency buttons
3	Keypad and display

The keypad

The CR 25.0 keypad features the following keys:

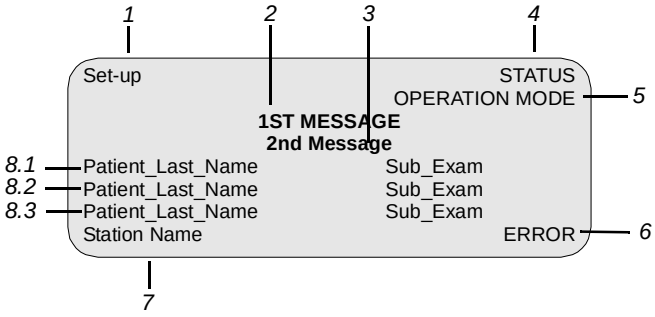
	Emergency key	To give an image priority to be sent to the image processing station if other images are already waiting in the image queue. This key can only be used for unidentified cassettes.
	Erase key	To erase images without digitizing them. This must be done if: • an image plate has not been used for more than 3 days; • an image plate has been exposed to an exceptionally high X-ray dose.
	Key-operator key	To access advanced functions (‘key-operator functions’).
	Service key	To access service-level functions. Reserved for trained service personnel.
	Escape key	To quit the current function or exit a menu without saving modifications.
	Confirm key	In key-operator mode: • to select a menu. • to accept an entry in a menu and go back to operator mode.

	Up key	• To move the cursor to the previous entry field. • To scroll upwards. • To increment the number in a numeric entry field.
	Down key	• To move the cursor to the next entry field. • To scroll downwards. • To decrement the number in a numeric entry field.
	Left key	• To scroll backwards through multiple choices within a field. • To move the entry position in a numerical entry field from right to left. • To toggle between values in a field.
	Right key	• To scroll forwards through multiple choices within a field. • To move the entry position in a numerical entry field from left to right. • To toggle between values in a field.

The display

The CR 25.0 control panel has a backlit LCD display with 8 lines of 40 characters each. Its lay-out depends on the operating mode.

- In **operator mode**, the display has dedicated areas for specific information:



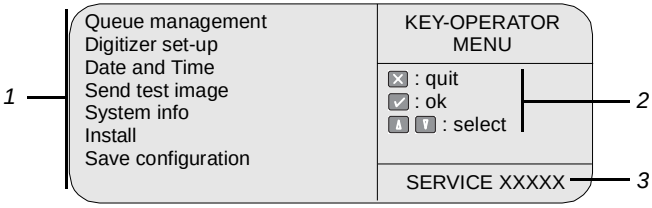
1	Set-up of image processing station: • [blank]: Default image processing station selected. • Off line: Transmission to all image processing stations disabled. • [process.station] not ready: Image processing station not available. • [process.station] rerouted: Images rerouted to other image processing station (ask the Agfa service technician if your system supports this configuration).
2	Type of message
3	Extra comment or action to take
4	System status: • READY: The CR 25.0 is ready for operation. • BUSY: The CR 25.0 is treating an image plate. • ERROR: An error has occurred. Refer to *'Troubleshooting checklist'* on page *54*. • LOCKED: id. • WARNING: id.

5	Operation mode: • [blank]: Normal operation mode. • EMERGENCY: Emergency function for image plates with ID data. • EMERGENCY BUTTON: Emergency function for image plates without ID data. • ERASURE: Re-erasure function. • DIRECT ID: Operation in dedicated configuration.
6	Error status: service code (SERVICE XXXXX) or error code (CODE XXXXX)
7	Station name of the CR 25.0
	Identifier of image plate being treated:
8.1	After image ID data is read;
8.2	During scanning of image plate and transmittal of image data;
8.3	During transmittal of image data to image processing station.

The operator main screen is:

When the CR 25.0 is treating an image plate, it displays the following screen:

- In **key-operator mode**, operation is menu driven. The menu displays the key-operator functions, the active keys, and the service code.



1	Key-operator functions
2	Active keys
3	Service code

- In **operator mode** and in **key-operator mode**, both informational and warning messages can be displayed. Informational messages are displayed as black text against a white background; warning messages are displayed in reverse mode.

The status indicator

The light at the top of the CR 25.0 indicates the status of the CR 25.0.

Color	Constant/ Flashing	Status	Action
Green	**Constant**	Ready.	Proceed.
	Flashing	• Busy (treating image plate). • Reading identification data of a cassette.	Wait.
Red	**Constant**	Error.	• Check display for messages. • Refer to *'Troubleshooting checklist'* on page *54*.
	Flashing	Initializing a cassette.	Wait.
	Flashing	• Locked or warning. • Power on/self-test in progress. • Key-operator mode. • Service mode. • CR 25.0 not connected to image processing station.	• Check display for messages. • Refer to *'Troubleshooting checklist'* on page *54*.

Emergency buttons

Two emergency buttons are located at the front of the CR 25.0. The emergency buttons determine the speed class, i.e. the sensitivity, which will be used to digitize the image plate. The sensitivity associated with the emergency buttons has been set during the configuration of your system. For more information, contact your local service organization.

The emergency buttons have the following labels:

	For digitizing images of the trunk.
	For digitizing images of the limbs.

- In the **interchangeable configuration**, the emergency buttons allow you to digitize emergency image plates without ID data.

- In the **dedicated configuration**, the emergency buttons allow you to digitize an image plate while you are entering the identification data via the ID Station.

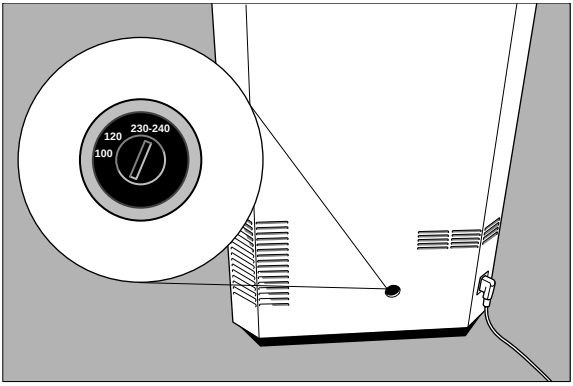
Audio signals

The CR 25.0 gives status information via beeps. The length of the beep indicates the response of the system to a key command.

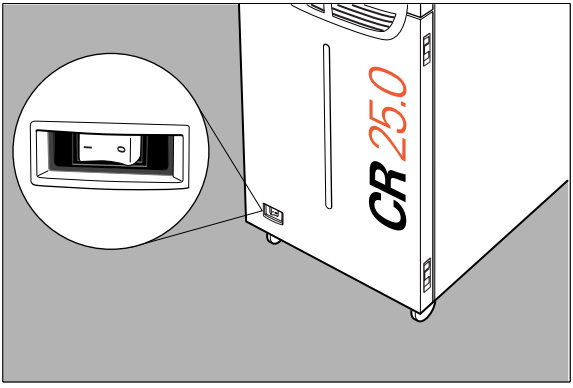
- A **short** beep means that CR 25.0 has accepted the key command and is starting the operation.
- A **long** beep means that you have pressed a non-active key or that the CR 25.0 has rejected the key command.
- An **interval** beep accompanies an error, locked or warning message. Refer to *'Troubleshooting checklist'* on page *54*.

Switching on the CR 25.0

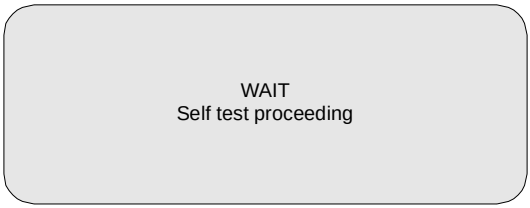
1 Make sure that the setting of the voltage selector at the back of the machine matches the power supply voltage.



2 Locate the main switch and place it in position ‘I’.



The machine starts a self-test which may take up to 3 minutes. The following screen is displayed:



❖ *During the self-test, you cannot activate any functions.*

If the CR 25.0 has completed the self-test successfully, the CR 25.0 enters the operator mode and displays the operator main screen:

❖ *If the CR 25.0 displays:*

... contact your local service organization.

Switching off the CR 25.0

Before switching off

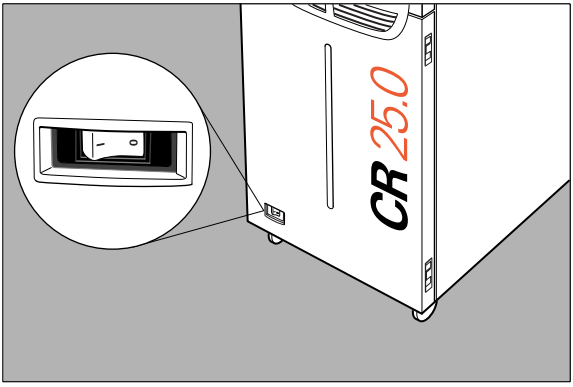
Check that the CR 25.0 is not scanning an image plate. If the CR 25.0 is scanning an image plate, the status indicator at the top of the machine is green and flashing.

Switching off

It is recommended to switch off the CR 25.0 at the end of the day.

Leave the CR 25.0 on if you intend to use it overnight. Switching on the CR 25.0 takes approximately 3 minutes. During this time emergency digitizing is not possible!

Place the main switch in position ‘0’.



Chapter 2

Basic operation (‘Operator mode’)

This chapter provides basic information on how to digitize image plates under normal conditions and in emergency situations. It also treats how to re-erase an image plate to prevent ghost images caused by previous exposures or by stray radiation. These functions are available in operator mode.

- ❑ Workflow
- ❑ Reading an image plate
- ❑ Reading an emergency image plate
- ❑ Re-erasing an image plate
- ❑ Reading the identification data of a cassette (Dedicated configuration only)
- ❑ Changing the image plate type (Dedicated configuration only)

Workflow

The workflow for identifying cassettes and digitizing image plates depends on the configuration of your system.

- In the **interchangeable configuration** a cassette is uniquely identified by the identification data in the cassette chip. Therefore, you must first identify the cassette via the ID Station with ID Tablet before you can digitize the image plate. Refer to *'Reading an image plate in the interchangeable configuration'* on page *29*.

  ❖ *An exception are emergency image plates which you can digitize without having identified the cassette. The unidentified emergency image plate will be given default ID data. Refer to 'Reading an emergency image plate in the interchangeable configuration' on page 35.*

- In the **dedicated configuration** the identification data are transmitted from the ID Station to the dedicated CR 25.0 via the network. Therefore, the CR 25.0 can digitize the image plate while you are entering the identification data on the ID Station. Refer to *'Reading an image plate in the dedicated configuration'* on page *32*.

Reading an image plate

The main function of the CR 25.0 is digitizing image plates and transmitting the digital image data to the preview station and the image processing station. The actual workflow depends on the configuration of your system.

Reading an image plate in the interchangeable configuration

In the interchangeable configuration, you must first identify the cassette via an ID Station with ID Tablet before you can digitize the image plate.

To read an image plate:

1 Make sure the cassette has been identified properly via the ID Station.

2 Check that the CR 25.0 is ready for operation:

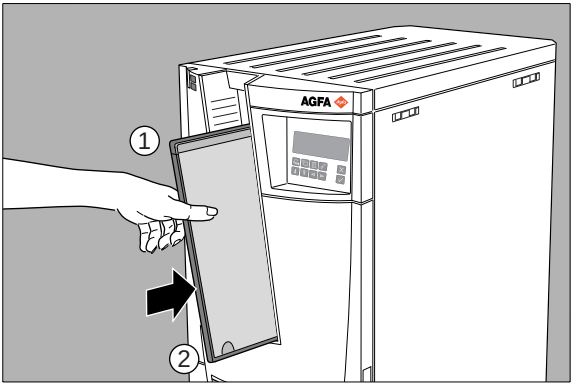
- The CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

❖ *The CR 25.0 is operational if the status field equals ‘READY’, even if status messages of the destination are shown (e.g. ‘QS not ready’).*

3 Insert the cassette containing the image plate into the cassette slot of the CR 25.0 as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



While treating the image plate, the CR 25.0 will display the following screen:

The CR 25.0:

- reads the cassette identification data;
- converts the information of the latent image to digital data;
- erases the image plate and re-inserts it into the cassette;
- gives the cassette ID data the status ‘erased’;
- returns the cassette;
- transmits the digital image data to the image processing station (‘destination’).

When the CR 25.0 has treated the cassette, it displays the operator main screen.

❖ *If the CR 25.0 displays an error message, refer to ‘Troubleshooting checklist’ on page 54.*

4 Remove the cassette from the cassette slot.

When the CR 25.0 returns the cassette, it is ready to be re-used immediately. However, if you leave it for more than 3 days before re-using it, you must re-erase it first. Refer to 'Re-erasing an image plate' on page 42.

Reading an image plate in the dedicated configuration

In the dedicated configuration, the CR 25.0 can digitize the image plate while you are entering the identification data via the ID Station.

To read an image plate:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with 'Ready' status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

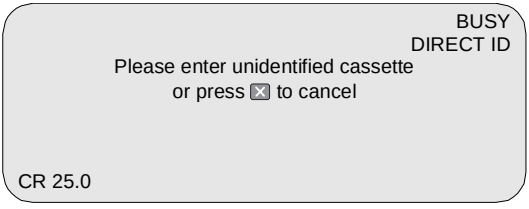
❖ *The CR 25.0 is operational if the status field equals 'READY', even if status messages of the destination are shown (e.g. 'QS not ready').*

2 Press the appropriate emergency button at the front of the CR 25.0.

The emergency button determines the speed class, i.e. the sensitivity, which will be used to digitize the image plate.

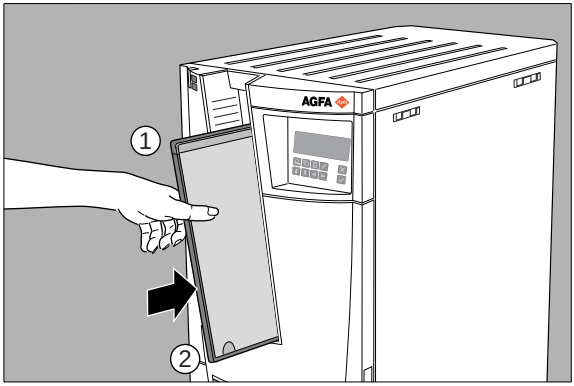
	For digitizing images of the trunk.
	For digitizing images of the limbs.

The button which you have pressed will be lit and the display will read:



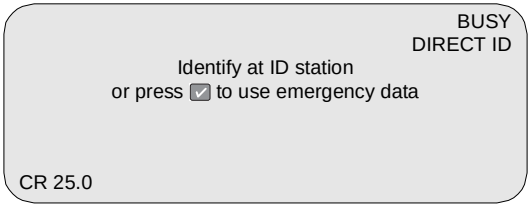
3 Insert the cassette containing the image plate into the cassette slot of the CR 25.0 as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



The CR 25.0 starts digitizing the image plate. You can enter the identification data, refer to step **4**.

While treating the image plate, the CR 25.0 will display the following screens:



The CR 25.0 converts the information of the latent image to digital data.

❖ *If the CR 25.0 displays an error message, refer to Chapter 3, 'Advanced operation ('Key-operator mode')'.*

4 Enter the identification data via the ID Station.

For detailed information, refer to the User manual of the ID Software.

As soon as you have entered the identification data, the CR 25.0 displays:

As soon as the CR 25.0 has digitized the entire image plate and you have entered the identification data:

- the CR 25.0 erases the image plate and re-inserts it into the cassette;
- the CR 25.0 gives the cassette ID data the status ‘erased’.
- the cassette is returned to the cassette slot;
- the digital image data is sent to the image processing station (‘destination’).

When the CR 25.0 has treated the cassette, it displays the operator main screen.

5 Remove the cassette from the cassette slot.

When the CR 25.0 returns the cassette, it is ready to be re-used immediately. However, if you leave it for more than 3 days before re-using it, you must re-erase it first. Refer to ‘Re-erasing an image plate’ on page 42.

Reading an emergency image plate

You may have an image plate which you wish to give priority over other image plates which are being processed by the image processing station. Such image plates are referred to as 'emergency image plates'. The actual workflow depends on the configuration of your system.

Reading an emergency image plate in the interchangeable configuration

In the interchangeable configuration, you can treat either:

- emergency image plates with ID data via the Emergency key on the keypad;
- emergency image plates without ID data via the emergency buttons at the front of the CR 25.0.

Reading emergency image plates with ID data

To read an emergency image plate with ID data:

1 Make sure the cassette has been identified properly via the ID Station.

2 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

❖ *The CR 25.0 is operational if the status field equals ‘READY’, even if status messages of the destination are shown (e.g. ‘QS not ready’).*

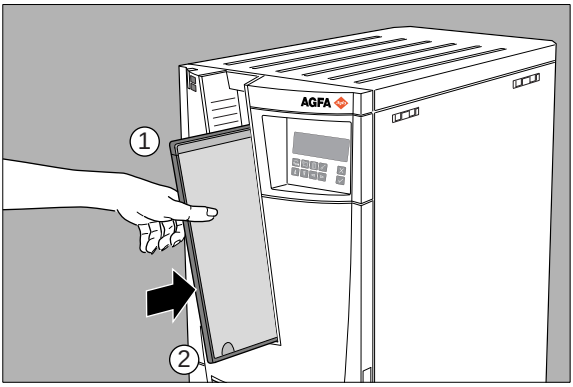
3 Press the Emergency key on the keypad.

The display will read:

The emergency status will only be assigned to the first image plate which you insert into the CR 25.0 cassette slot after pressing the Emergency key.

4 Insert the cassette containing the emergency image plate into the cassette slot as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



When the CR 25.0 has treated the emergency image plate, it displays the operator main screen. The image processing station will give the emergency image priority over the other images in the image processing queue.

❖ *If you do not enter a cassette within 1 minute after pressing the Emergency key or if you enter a cassette without ID data, the CR 25.0 will quit the emergency function and return to the operator main screen.*

5 Remove the cassette from the cassette slot.

Reading emergency image plates without ID data

To read an emergency image plate without ID data:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

❖ *The CR 25.0 is operational if the status field equals ‘READY’, even if status messages of the destination are shown (e.g. ‘QS not ready’).*

2 Press the appropriate emergency button at the front of the CR 25.0.

The emergency button determines the speed class, i.e. the sensitivity, which will be used to digitize the image plate.

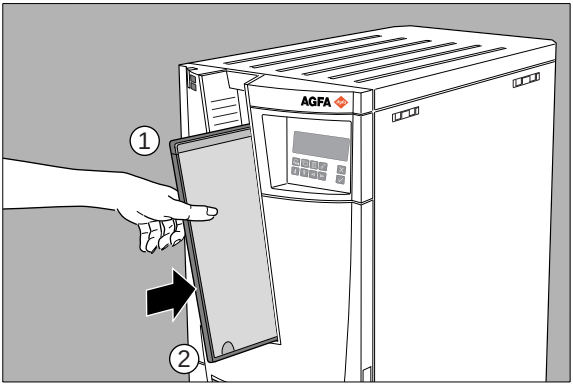
	For digitizing unidentified emergency images of the trunk.
	For digitizing unidentified emergency images of the limbs.

The button which you have pressed will be lit and the display will read:

The emergency status will only be assigned to the first image plate which you insert in the CR 25.0 cassette slot after pressing the emergency button.

3 Insert the cassette containing the emergency image plate into the cassette slot as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



The image plate will be digitized using the speed class, i.e. the sensitivity, corresponding to the emergency button as defined during configuration.

When the CR 25.0 has treated the emergency image plate, it displays the operator main screen. The digital image data are transmitted to the image processing station accompanied by default ID data. The image processing station will give the emergency image priority over the other images in the image processing queue.

- *If you do not enter a cassette within 15 seconds after pressing the emergency button, the CR 25.0 will quit the emergency button function and return to the operator main screen.*

- *To change the speed class corresponding to the emergency button, contact your local service organization.*

4 Remove the cassette from the cassette slot.

Reading an emergency image plate in the dedicated configuration

In the dedicated configuration, you can digitize unidentified emergency image plates. The digital image data will be assigned default ID data.

To digitize an emergency image plate, you must press the Confirm key after you have inserted the cassette (refer to step 4). Image data transmission to the preview and the image processing station will be suspended until you have pressed the Confirm key.

To read an emergency image plate:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with 'Ready' status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

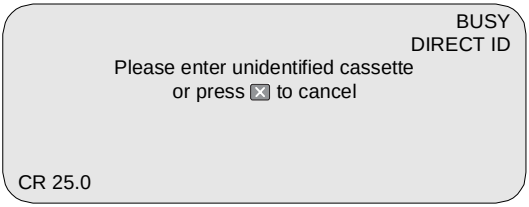
❖ *The CR 25.0 is operational if the status field equals 'READY', even if status messages of the destination are shown (e.g. 'QS not ready').*

2 Press the appropriate emergency button at the front of the CR 25.0.

The emergency button determines the speed class, i.e. the sensitivity, which will be used to digitize the image plate.

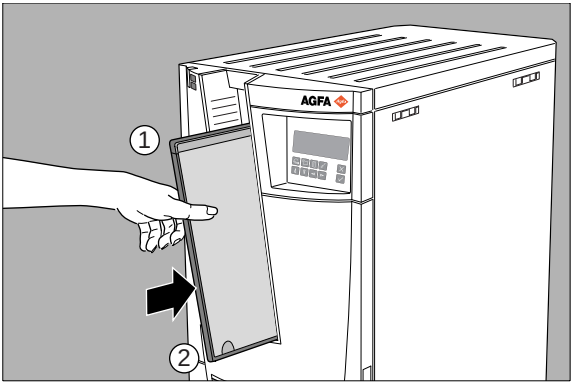
	For digitizing images of the trunk.
	For digitizing images of the limbs.

The button which you have pressed will be lit and the display will read:



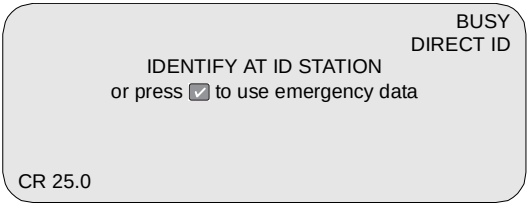
3 Insert the cassette containing the image plate into the cassette slot of the CR 25.0 as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



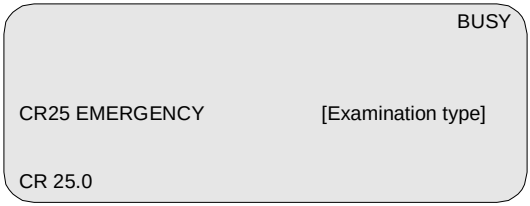
The CR 25.0 starts digitizing the image plate.

While treating the image plate, the CR 25.0 will display the following screen:



4 Press the Confirm key.

The CR 25.0 displays:



- If you pressed the emergency button for digitizing images of the limbs, [Examination type] equals ‘Extremities‘.
- If you pressed the emergency button for digitizing images of the trunk, [Examination type] equals ‘Corpus’.

When the CR 25.0 has treated the emergency image plate, it displays the operator main screen. The digital image data are transmitted to the image processing station accompanied by default ID data. The image processing station will give the emergency image priority over the other images in the image processing queue.

5 Remove the cassette from the cassette slot.

Re-erasing an image plate

At the end of a normal or emergency digitizing cycle, the CR 25.0 returns an erased image plate. However, in the following cases, you must re-erase the image plate before re-using it in order to prevent ghost images from interfering with the image of interest:

- If the image plate has not been used for more than 3 days.
  In this case, the image plate may have been exposed to stray radiation.
- If an image plate has been exposed to an exceptionally high X-ray dose.
  In this case, deep layers of the image plate may still retain a latent image after standard erasure. Leave the image plate to rest at least one day before re-erasing it.

You can erase image plates which you have given the status ‘to be erased’ via the ID Station or image plates which have the status ‘erased’.

Re-erasing image plates with status ‘erased’

To re-erase an image plate which has been erased as part of a normal or emergency digitizing cycle:

1 Check that the CR 25.0 is ready for operation:

- the CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

- the status indicator at the top of the CR 25.0 must be green and be lit constantly.

2 Press the Erase key on the keypad.

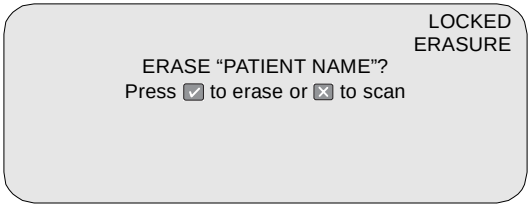
The display will read:

3 Insert the cassette into the cassette slot.

While erasing, the CR 25.0 will still display the above screen. When the CR 25.0 has erased the image plate, it displays the operator main screen.

Warning

If the above screen is not displayed but the display reads:



you have entered a cassette with ID data not having the status ‘erased’. You now have the choice, either cancel erasing or erase the image plate.

- To cancel erasing and make a regular scan: press the Escape key.

- To erase the image plate: press the Confirm key.

While erasing, the CR 25.0 will display:

When the CR 25.0 has erased the image plate, it displays the operator main screen.

4 Remove the cassette from the cassette slot.

Re-erasing image plates with status ‘to be erased’

To re-erase an image plate which you have given the status ‘to be erased’ via the ID station:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

2 Insert the cassette into the cassette slot.

The CR 25.0 will automatically erase the image plate. The display will read:

When the CR 25.0 has erased the image plate, it displays the operator main screen.

3 Remove the cassette from the cassette slot.

Reading the identification data of a cassette (Dedicated configuration only)

In the dedicated configuration, the identification data stored in the memory chip of the cassette can be read via the CR 25.0.

To read the identification data of a cassette:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with ‘Ready’ status, e.g.:

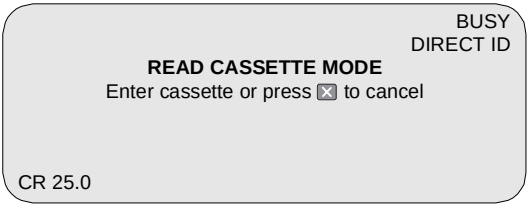
- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

❖ *The CR 25.0 is operational if the status field equals ‘READY’, even if status messages of the destination are shown (e.g. ‘QS not ready’).*

2 In the ID Software on the ID Station, select the mode for reading cassettes.

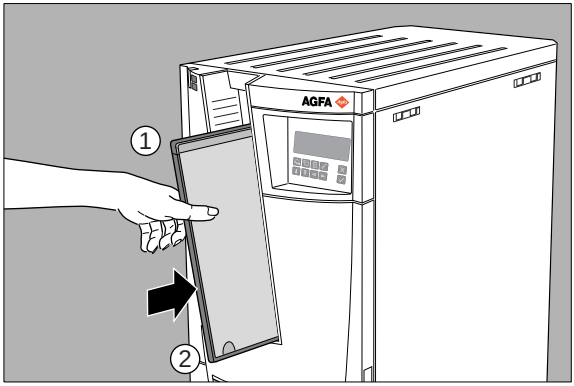
Refer to the User manual of the ID Software.

The display of the CR 25.0 will read:



3 Insert the cassette containing the image plate into the cassette slot of the CR 25.0 as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



While the CR 25.0 reads the identification data from the cassette chip, the status indicator at the top of the machine is red and flashing.

The identification data will be displayed on the ID Station. Subsequently, the CR 25.0 returns the cassette to the cassette slot and displays the operator main screen.

4 Remove the cassette from the cassette slot.

Changing the image plate type (Dedicated configuration only)

If you use new generation ADC phosphor plates, the cassettes containing the plates must first be initialized. The new generation of plates can be identified by the plate type and the initializing code printed on the back (e.g. MD 30 19).

If you purchased cassettes already containing ADC phosphor plates, the cassettes are ready for use. If you purchased ADC phosphor plates or cassettes separately, the cassettes must be initialized first.

In the dedicated configuration, you can initialize cassettes via the CR 25.0.

To initialize a cassette:

1 Check that the CR 25.0 is ready for operation:

- The CR 25.0 must display the operator main screen with 'Ready' status, e.g.:

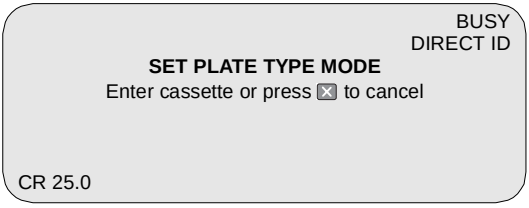
- The status indicator at the top of the CR 25.0 must be green and be lit constantly.

❖ *The CR 25.0 is operational if the status field equals 'READY', even if status messages of the destination are shown (e.g. 'QS not ready').*

2 In the ID Software on the ID Station, select the mode for initializing cassettes.

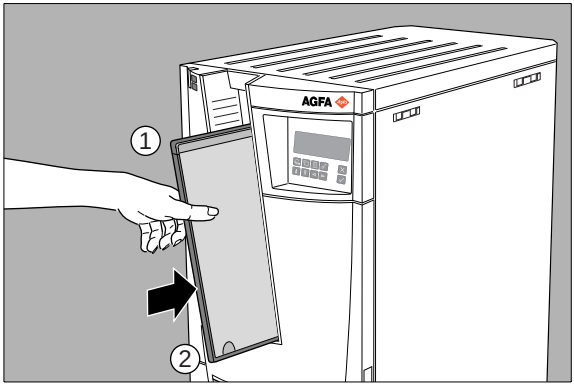
Refer to the User manual of the ID Software.

The display of the CR 25.0 will read:



3 Insert the cassette containing the image plate into the cassette slot of the CR 25.0 as shown below.

Make sure to insert the cassette with the hinge [1] at the top and the locking mechanism [2] at the bottom.



4 Enter the initialization code in the ID Software.

Refer to the User manual of the ID Software.

While the CR 25.0 initializes the cassette, the status indicator at the top of the machine is red and flashing.

When the cassette has been initialized, the CR 25.0 returns the cassette to the cassette slot and displays the operator main screen.

5 Remove the cassette from the cassette slot.

Chapter 3

Advanced operation (‘Key-operator mode’)

This chapter gives an overview of the key-operator functions, preventive maintenance actions and troubleshooting. For detailed information on these topics, refer to the Reference manual.

- ❑ Survey of advanced functions (‘Key-operator mode’)
- ❑ Checking the image quality
- ❑ Troubleshooting checklist

Survey of advanced functions (‘Key-operator mode’)

A survey of the functions which are available in key-operator mode is given below. For detailed information, refer to *Chapter 3, ‘Advanced operation (‘Key-operator mode’)’* of the CR 25.0 Reference manual.

Function in key-operator main menu	Section in Reference manual	Page
Queue management	*‘Consulting the image transmission queue (‘Queue management’)’*.	*54*
Digitizer set-up	*‘Customizing the CR 25.0 (‘Digitizer set-up’)’*.	*58*
Date and Time	*‘Setting the date and time’*.	*63*
Send test image	*‘Sending test images’*.	*64*
System info	*‘Consulting information on the CR 25.0’*.	*65*
Install	*‘Installing a new software version’*. *‘Installing a new language’*. *‘Installing new customer parameters’*.	*65* *75* *81*
Save configuration	*‘Saving the configuration data on a diskette (backup)’*.	*87*

Checking the image quality

The only maintenance action which you must perform is checking the image quality. Refer to the Reference manual of the image processing system.

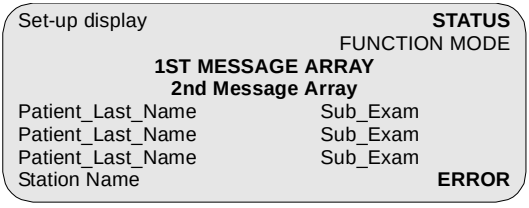
Troubleshooting checklist

A survey of possible problems is listed below. If corrective actions are straightforward, they are given below. The more elaborate troubleshooting procedures are explained in detail in *Chapter 4, 'Preventive maintenance and troubleshooting'* of the CR 25.0 Reference manual.

General errors

Error	Action
The CR 25.0 does not start up.	Refer to *'Checking the voltage supply'* on page *103* of the Reference manual.

Errors during operation



Status field:	**ERROR**
Error field:	'SERVICE XXXXX'
Contact your local service organization.	

Status field:	**ERROR**	
Error field:	'CODE XXXXX'	
MESSAGE 1	**Message 2**	**Action**
POWER SUPPLY OUT OF TOLERANCE	1. Check setting of voltage selector switch on back panel. 2. Check fuses of the machine 3. Check supply voltage.	Refer to *'Checking the voltage supply'* on page *103* of the Reference manual.

Status field: Error field:	**ERROR** 'CODE XXXXX'	
IP JAM	1. Remove right side panel 2. Put plate back into cassette. 3. Close right side panel.	Refer to *'Solving image plate and cassette jams'* on page *106* of the Reference manual.

Status field:	**WARNING**	
MESSAGE 1	**Message 2**	**Action**
ERASURE LAMP [X], [Y], [Z] DEFECTIVE	Press ☑ to complete, IP is not erased	• Press Confirm key. • Refer to *'Replacing the erasure lamps'* on page *98* of the Reference manual.
SCANNER WARNING	Possible bad image, press ☑	• Press Confirm key. • Contact your local service organization.
[PPNAME] NOT READY	Please check and press ☑	• Check image processing station. • If image processing station is ready, press Confirm key.
CORRUPTED MESSAGE IN QUEUE	Please press ☑ and check queue	• Press Confirm key. • Refer to *'Consulting the image transmission queue ('Queue management')'* on page *54* of the Reference manual.
UNKNOWN DESTINATION [PPNAME]	Please press ☑ and check queue	• Press Confirm key. • Refer to *'Consulting the image transmission queue ('Queue management')'* on page *54* of the Reference manual.
ERROR WHILE LOADING LANGUAGE FILE	Default language is used, please press ☑	• Press Confirm key. English will be used. • Restart CR 25.0. • If the problem persists, contact your local service organization.

Status field:	WARNING	
MESSAGE 1	**Message 2**	**Action**
PARTLY SCANNED IP DETECTED	Possible loss of image, press ☑	• Press Confirm key. • Check image at destination.

Status field:	LOCKED	
MESSAGE 1	**Message 2**	**Action**
IP NOT SUFFICIENTLY ERASED	Press ☑ and erase again	• Press Confirm key. • Refer to *'Re-erasing an image plate'* on page *42*.
EMPTY CASSETTE	Press ☑ to get cassette	• Press Confirm key. • Remove cassette. • Insert cassette containing image plate.
CASSETTE WRITE ERROR	Press ☑ to get cassette	• Press Confirm key. • Remove cassette. • Use another cassette. • If problem persists with other cassettes, contact your local service organization.
WRONG CASSETTE	Press ☑ and remove cassette.	• Press Confirm key. • Remove cassette. • Insert correct cassette in the right way.
CASSETTE IDENTIFICATION ERROR	Press ☑, remove and identify	• Press Confirm key. • Remove cassette. • Re-identify cassette. • Re-insert cassette.
CASSETTE READ/ WRITE ERROR	Press ☑, remove and try again	• Press Confirm key. • Remove cassette. • Re-insert cassette. • If problem persists, initialize and identify cassette via ID Station. • If problem persists with other cassettes, contact your local service organization.

Status field:	LOCKED	
MESSAGE 1	**Message 2**	**Action**
CASSETTE NOT IDENTIFIED	Press ☑, remove and identify	• Press Confirm key. • Remove cassette. • Identify cassette. • Re-insert cassette.
24 X 30 CM CALIBRATION MISSING	Press ☑ to accept or ☒	• Press Confirm key to treat 24 x 30 cm image plate without calibration or press Cancel key to treat cassettes with other formats. • Contact your local service organization.
SERVICE MODE	Please wait	Wait.
CASSETTE SLOT BLOCKED	Remove cassette, press ☑	• Remove cassette. • Remove obstructing objects. • Press Confirm key.
IMAGE-QUEUE FULL	Check queue	• Refer to *'Consulting the image transmission queue ('Queue management')'* on page *54* of the Reference manual. • Check that the CR 25.0 is not off line (Refer to *'The display'* on page *19*).
UNKNOWN DESTINATION [PPNAME]	Press ☑, remove cassette and identify	• Press Confirm key. • Remove cassette. • Identify cassette. • Re-insert cassette. • Check the configuration of the system.
RIGHT SIDE PANEL NOT CLOSED	Close right side panel	Close the right side panel.
UNKNOWN IP-TYPE	Press ☑, remove cassette, call Service.	• Press Confirm key. • Remove cassette. • Contact your local service organization.
EMERGENCY DATA NOT DEFINED	Emergency keys disabled, press ☑	• Press Confirm key • Contact your local service organization.

Errors when handling diskettes

Error	Action
Wrong or missing volume label	• Remove floppy. • Insert floppy with correct label. • Press Confirm key.
Floppy not formatted	• Remove floppy. • Insert formatted floppy. • Press Confirm key.
Floppy full	• Remove floppy. • Insert empty formatted floppy. • Press Confirm key.
Floppy write protected	• Remove floppy. • Remove write protection from floppy. • Re-insert floppy. • Press Confirm key.

Appendix A

Equipment information sheet

Specifications

Product description	
Type of product	Digitizer
Commercial name	CR 25.0
Model number	5156
Original seller/manufacturer	Agfa-Gevaert NV-Mortsel
Labelling	
CE	93/42 EEC ‘Medical Devices’ (Europe)
UL	UL 60601-1 and CSA 22.2 No. 601-1 (North America)
CUL	(North America)
Dimensions	
Length, at cassette slot	750 mm
Length, at foot	710 mm
Width	450 mm
Height	1408 mm
Weight	
Unpacked	277 kg
Electrical connection	
Operating voltage	• 230 V / 240 V ± 10% • 120 V ±10% • 100 V ± 10%
Mains fuse protection	Europe: 16 A, slow blow USA & Japan: 15 A, slow blow
Mains frequency	50/60 Hz

Power consumption	
Standby	
• 230 V/ 50 Hz configuration	230 W
• USA: 120 V/ 60 Hz configuration	216 W
• Japan: 100 V/ 60 Hz	220 W
During operation	
• 230 V/ 50 Hz configuration	max. 1610 W
• 120 V/ 60 Hz configuration (USA)	max. 1440 W
• 100 V/ 60 Hz (Japan)	max. 1500 W
Environmental requirements	
Room temperature	15 °C - 30 °C
Maximum temperature change	0.5 °C/min.
Relative humidity	15 % - 80 %
Magnetic field (Dynamic)	compliant with EN 61000-4-8, Level 5
Sunlight exposure	not be operated in full sunlight
Warming-up time	
• Cold start	fully operational after max. 30 min.
• Warm start	fully operational after self-test if not switched off for more than 3 min., after 30 min. operation
Cassette format	**corresponding IP format**
24 x 18 cm	238 x 178 mm
30 x 24 cm	298 x 238 mm
35 x 35 cm	354 x 354 mm
35 x 43 cm	354 x 430 mm
30 x 15 cm	298 x 148 mm
12 x 10”	303 x 252 mm
10 x 8”	252 x 201 mm

Physical emissions	
Noise emission (sound power level according to ISO 7779)	
• During scanning	max. 65 dB(A)
• Standby	max. 45 dB(A)
Radio frequency emission	according to EN 55022:1997, Class B and Radio frequency emission FCC, Part 15, Subchapter B, Class A
Heat emission	
• During scanning	max. 1610 W
• Standby	230 W
Cassette return time	51 - 95 secs
End of Life	
Estimated product life (if regularly serviced and maintained according to Agfa instructions)	7 yrs.

Appendix B

ADC Compact cassette

Safety precautions

Observe great care whenever removing the image plate from the ADC Compact cassette. Refer to the cleaning procedure described further on in this manual.

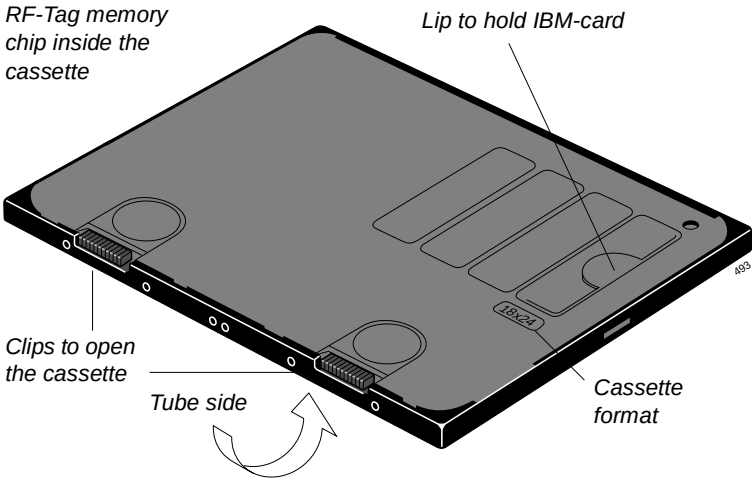
Make sure that the automatic exposure control device is placed above the cassette, to prevent patients from receiving an overdose of X-rays. When it is located underneath the cassette, the backscatter protection (lead) contained in the red side of the cassette, retains a certain amount of X-rays. The dose measured by the cell will then be much lower than the dose actually given to the patient.

❖ *The image plate causes a specific X-ray scattering. This influences the response of the exposure control device. To compensate for this, recalibration of the device for the use with ADC Compact cassettes could be necessary.*

Description of the ADC Compact cassette

The ADC Compact cassette and plate are compatible with existing X-ray tables. The exposure equipment and routines do not have to be modified when switching from conventional to digital imaging. Although compatible with existing X-ray equipment, an ADC Compact cassette is quite different from a conventional cassette. The most important difference lies inside, in the image receptor.

ADC Compact cassettes and ADC 70 cassettes are not interchangeable. But the same image plates can be used for both.



Embedded memory

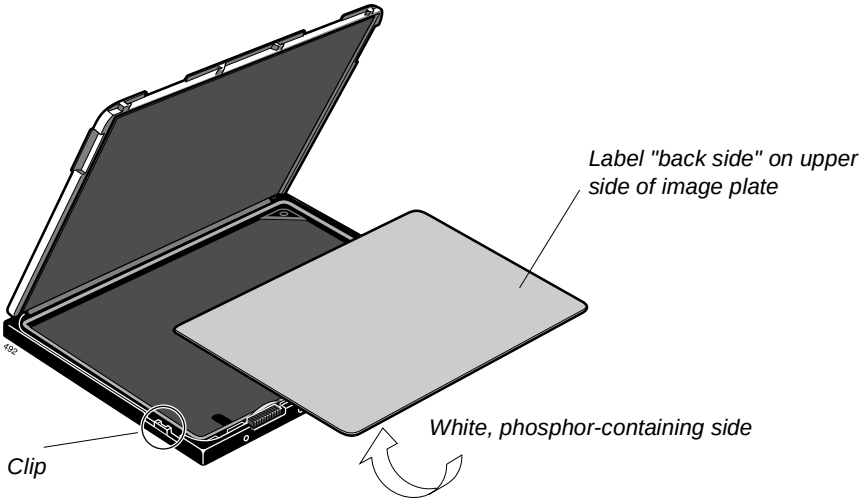
The main difference lies in the RF-tag memory chip that is permanently mounted in the cassette. Using the ID Software you can enter patient demographics and examination data into the memory chip. The identification of this data is performed by no-touch radiofrequency tagging via a built-in antenna card in the ADC Compact cassette.

Image plate

Another difference between an ADC Compact cassette and a conventional cassette is the X-ray sensitive element (image receptor). The latter is no longer a film, but an image plate that can be re-used thousands of times.

The way in which this image plate is placed into the cassette is of great importance. The side containing the white phosphor must be oriented towards the black tube side of the cassette. The dark support side is then oriented towards the red side of the cassette, as shown in the illustration below.

The ‘clips’ mounted on the cassette prevent the cassette from being opened by a conventional daylight system such as the Curix Capacity (Plus), so that even in hybrid conventional/digital departments the occurrence of errors is avoided.



Cleaning the image plate

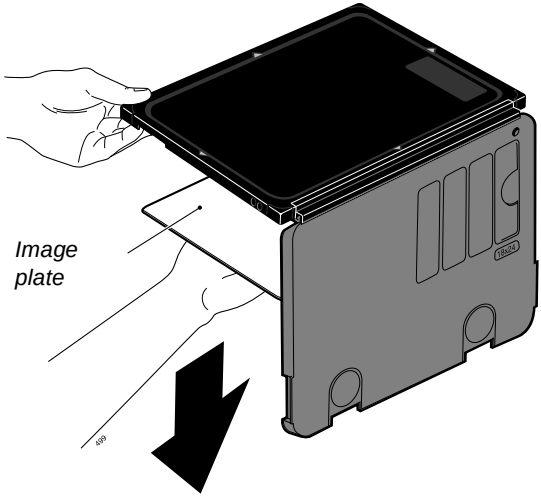
The inner lining of the ADC Compact cassette body is made of Bayer Makrolon polycarbonate. This ensures a high degree of protection against electrostatic charging and dust collection on the ADC image plates. Nonetheless, it is recommended to clean the image plates once a month using the following procedure:

1 Open the cassette with the red side up.

2 Put your hand on the image plate with the cassette in a horizontal position. Make sure that you do not press on the plate.

3 Turn the cassette over, holding the image plate in position with your other hand.

4 Take away the cassette. The image plate remains lying on your hand.



5 When necessary, clean extreme contamination with ADC Digital Screen Cleaner.

6 Moisten a cellulose cloth (non-fluffy) with the cleaning agent.

7 Rub the cleaner softly and evenly over the whole surface of the screen.

8 Leave the cassette with the clean screens open for approximately 10 minutes to enable the solvent to evaporate.

9 Reassemble the cassette.

Make sure that the white side of the image plate, containing the phosphor, is oriented towards the (black) tube side of the cassette.

> ***Ensure that the image plate is within the flange on the inside of the cassette. If you put the image plate into the cassette differently, e.g. if the image plate lies partly in between the hinge of the cassette, it can be irreparably damaged.***

Cleaning the cassettes

When necessary, you can clean the outside of the ADC cassettes with soft water and soap or a detergent solution, with ADC Digital Screen Cleaner or with benzine. The inside should always be cleaned with ADC Digital Screen Cleaner.

Never clean the cassette with ethyl alcohol, methyl alcohol or diethylic ether.

Technical specifications of the ADC Compact cassette

Sizes

- 35 x 43 cm (14 x 17")
- 35 x 35 cm (14 x 14")
- 24 x 30 cm
- 18 x 24 cm
- 8 x 10"
- 10 x 12"
- 21 x 43 cm (by partial scan of dedicated 35 x 43 cm cassettes)
- 35 x 43 cm HR high resolution cassette
- 35 x 35 cm HR high resolution cassette
- 15 x 30 cm dental cassette

Standards

- DIN 6832 part 1 & 2
- ANSI/NAPM IT 1.49-1995
- IEC 406 (draft 1995)

Weight

- 35 x 43 cm typical 1.6 kg

Material

- Body — ABS (Acrylonitryl Butadiene Styrene)
- Corners — Polyurethane Rubber (PUR)
- Hinge — Polypropylene (PP)
- Inner lining — Makrolon

Identification

- Memory chip (RF-tag card) embedded in the cassette

Backscatter protection

- 150 μ lead

Technical specifications of the image plate

Sizes

- 35 x 43 cm (14 x 17")
- 35 x 35 cm (14 x 14")
- 24 x 30 cm
- 18 x 24 cm
- 8 x 10"
- 10 x 12"
- 15 x 30 cm

Plate construction

Protective layer	Electron beam cured polymer
Phosphor	BaSrFBrI:Eu
Base	P.E.T.

Characteristics

Its luminescence spectrum is the typical Eu^{2+} -luminescence, which is at around 390 nm in lattices of the BaFBr-type. The top in the luminescence spectrum is shifted slightly to longer wavelengths due to the incorporation of iodide.

The stimulation spectrum is much broader than that of pure BaFBr and is shifted to longer wavelengths. This shift is caused in the first place by the partial replacement of Ba by Sr, and in the second place by the incorporation of iodide. Thanks to the red-shift of the stimulation spectrum, maximum stimulability is assured at 633 nm, the wavelength of the stimulating laser.

The Agfa phosphor has excellent dark decay characteristics. Two hours after exposure, approximately 80% of the energy stored upon exposure is still available. The image retention is greater than 50% up to 24 hours after irradiation.

Appendix C

Remarks for HF-emission and immunity

Remarks for HF-emission and immunity

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Transmission Measurements	Agreement	Electromagnetic Environment Guidelines
High frequency transmissions in accordance with CISPR 11	Group 1	The device uses high frequency energy exclusively for its internal functions. For this reason, its high frequency transmission is very low and it is improbable that neighboring electronic equipment will be disrupted.
High frequency transmissions in accordance with CISPR 11	Class B	The device is intended for use in all buildings, including living areas and areas directly connected to a public supply network that also supplies buildings that are used for domestic purposes.
Excess oscillations in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flickering in accordance with IEC 61000-3-3	Fulfilled	

This device was tested for a normal hospital environment as described above. Nevertheless the HF-emission and immunity can be influenced by connected data cables depending on length and the manner of installation.

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Resistance to Jamming Test	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment Guidelines
Discharge of static electricity in accordance with IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood, concrete or ceramic tiles. The relative humidity must be at least 30%, if the floor is made of synthetic material.
Fast transient electrical disturbance variables / bursts in accordance with IEC 61000-4-4	± 2 kV for network leads ± 1 kV for entry and outlet leads	± 2 kV for network leads ± 1 kV for entry and outlet leads	The quality of the voltage supplied should correspond to a typical commercial or clinical environment.
Impulse voltages (surges) in accordance with IEC 61000-4-5	± 1 kV push-pull voltage ± 2 kV common mode voltage	± 1 kV push-pull voltage ± 2 kV common mode voltage	The quality of the voltage supplied should correspond to that of a typical commercial or clinical environment.
Voltage breakthroughs, short term interruptions and variations in the voltage supplied in accordance with IEC 61000-4-11	• < 5% U_r (> 95% breakthrough of U_r) for ½ period • 40% U_r (> 60% breakthrough of U_r) for 5 periods • 70% U_r (30% breakthrough of U_r) for 25 periods • < 5% U_r (95% breakthrough of U_r) for 5 s	• < 5% U_r (> 95% breakthrough of U_r) for ½ period • 40% U_r (> 60% breakthrough of U_r) for 5 periods • 70% U_r (30% breakthrough of U_r) for 25 periods • < 5% U_r (95% breakthrough of U_r) for 5 s	The quality of the voltage supply should correspond to that of a typical commercial or clinical environment. If the user wants the device to work continuously, even when the energy supply is interrupted, it is recommended to use an energy supply free of interruptions or a battery.
Magnetic field at the supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	3 A/m	3 A/m	Magnetic field at the network frequency should correspond to the typical values as they are in a commercial and clinical environment.
• REMARK : U_r is the alternating current in the network before the application of the test level.			

This device is intended for operation in the electromagnetic environment given below. The user of the device should ensure that it is used in such an environment.

Tests of Resistance to Disruption	IEC 60601 Test Level	Level of Agreement	Electromagnetic Environment
			Use portable and mobile radio sets at a safe distance from the device (including the leads) not closer than the recommended protective distance, which is calculated according to the equation suitable for the transmission frequency. Recommended protective distance:
Conducted high frequency disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d = 1.2 \sqrt{P}$
Radiated high frequency disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			With P as the rated power of the transmitter in watts (W) in accordance with the manufacturer information on the transmitter and d as the recommended protective distance in metres (m). The field strength of stationary radio transmitters is lower than the level of the agreement[a] at all frequencies in accordance with an on-site investigation[b]. Disruptions are possible near devices that carry the following symbol:

- REMARK 1: The higher value will apply at 80 MHz and 800 MHz.
- REMARK 2: These Guidelines may not apply to all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

a. The field strength of stationary transmitters, such as base stations of radio telephones, mobile broadcasts for rural areas, amateur stations, and AM and FM radio transmitters, cannot be precisely predetermined theoretically. An investigation of the location is recommended, to ascertain the electromagnetic environment as a result of stationary high frequency transmitters. If the field strength of the device exceeds the level of agreement given above, the device must be observed with regard to its normal operation at each place of use. In case of unusual performance characteristics, it can be necessary to take additional measures, such as the re-orientation of the device, for example.
b. The field strength will be lower than 3 V/m above the frequency range from 150 kHz to 80 MHz.

This device is intended for operation in an electromagnetic environment in which the radiated high frequency disturbance variables are monitored. The user of the device can help to prevent electromagnetic disruptions by maintaining the minimum distances between portable and mobile high frequency communication equipment (transmitters) and the device as recommended below, in accordance with the maximum output power of the communications equipment.

Recommended Protective Distances between Portable and Mobile High Frequency Communication Equipment and the Device			
Rated Power of the Transmitter W	Protective Distance in accordance with Transmission Frequency m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

The distance can be determined through the equation for each respective column.
P is the rated power of the transmitter in watts (W) according to the manufacturer information on the transmitter, only for transmitters where the rated power is not mentioned in the above table.

- REMARK 1 : An additional factor of 10/3 has been used to calculate the recommended protective distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, to reduce the probability that mobile portable communication equipment unintentionally brought into the area of the patients will lead to a disruption.
- REMARK 2 : These Guidelines may not be relevant in all situations. The dispersion of electromagnetic waves is influenced by absorption and reflections from buildings, objects and people.

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